EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to fruits and/or vegetables (ID 1212, 1213, 1214, 1217, 1218, 1219, 1301, 1425, 1426, 1427, 1428, 1429, 1430) and to the “Mediterranean diet” (ID 1423) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

EFSA Publication

Link to article, DOI:
10.2903/j.efsa.2011.2245

Publication date:
2011

Document Version
Publisher's PDF, also known as Version of record

European Food Safety Authority

EFSA Journal 2011;9(6):2245

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to fruits and/or vegetables (ID 1212, 1213, 1214, 1217, 1218, 1219, 1301, 1425, 1426, 1427, 1428, 1429, 1430) and to the "Mediterranean diet" (ID 1423) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to fruits and/or vegetables and to the "Mediterranean diet". The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

Fruits and/or vegetables

The foods that are the subject of the health claims are "fruits (fresh, frozen, canned, bottled, dried, juiced)", "fruit-rich diet", "vegetables (fresh, frozen, canned, bottled, dried, juiced)", "vegetable-rich diet", and "fruits and vegetables" related to the following claimed effects: cardiac function, weight management, and blood glucose control.

The Panel notes that the type and amount of the specific fruits/vegetables and/or of the fruit/vegetable products required to obtain the claimed effects have not been indicated in the information provided; that the macro- and micronutrient composition, and the energy density, of different fruits and fruit products, and of different vegetables and vegetable products, is very variable; and that the significant differences in composition existing between such fruit/vegetable products may have an impact on the claimed effects. The Panel also notes that the health effects of "fruit-rich" and "vegetable-rich" diets

[1] On request from the European Commission, Question No EFSA-Q-2008-1950, EFSA-Q-2008-1951, EFSA-Q-2008-1952, EFSA-Q-2008-1955, EFSA-Q-2008-1956, EFSA-Q-2008-1957, EFSA-Q-2008-2039, EFSA-Q-2008-2160, EFSA-Q-2008-2162, EFSA-Q-2008-2163, EFSA-Q-2008-2164, EFSA-Q-2008-2165, EFSA-Q-2008-2166, EFSA-Q-2008-2167, adopted on 08 April 2011.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to fruits and/or vegetables (ID 1212, 1213, 1214, 1217, 1218, 1219, 1301, 1425, 1426, 1427, 1428, 1429, 1430) and to the "Mediterranean diet" (ID 1423) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2245. [19 pp.]. doi:10.2903/j.efsa.2011.2245. Available online: www.efsa.europa.eu/efsajournal

may depend on the overall characteristics (e.g. energy, energy density, and macronutrient composition) of such diets as influenced by other foods.

The references submitted for the scientific substantiation of the health claims included narrative reviews and consensus opinions which addressed the association between dietary patterns and lifestyle factors (e.g. physical activity) on the risk of chronic disease, including coronary heart disease, obesity and type 2 diabetes. Dietary patterns which include a high consumption of fruits and vegetables have been associated with a decreased risk of chronic diseases (e.g. coronary heart disease, obesity and type 2 diabetes) as compared to dietary patterns, amongst others, characterised by low consumption of fruits and vegetables. However, the food items which are included in the "fruit" and "vegetable" categories are generally not reported in these studies, and the evidence provided by these studies relates to overall dietary patterns rather than to an effect of "fruit" and "vegetable" consumption independent of other dietary modifications. Accordingly, dietary recommendations for the primary prevention of such diseases generally include consumption of a diet rich in fruits and vegetables, together with an appropriate intake of other foods to achieve dietary balance of fat/fatty acids, carbohydrates, adequate intake of dietary fibre and limited intake of sodium and alcohol.

The Panel considers that because of the high variety of the foods and food products that are the subject of the health claims, "fruits (fresh, frozen, canned, bottled, dried, juiced)", "fruit-rich diet", "vegetables (fresh, frozen, canned, bottled, dried, juiced)", "vegetable-rich diet", "fruits and vegetables", these foods are not sufficiently characterised in relation to the claimed effects proposed.

On the basis of the data presented, the Panel concludes that a cause and effect relationship cannot be established between the consumption of "fruits (fresh, frozen, canned, bottled, dried, juiced)", "fruit-rich diet", "vegetables (fresh, frozen, canned, bottled, dried, juiced)", "vegetable-rich diet" or "fruits and vegetables" and the claimed effects proposed because of the insufficient characterisation of these food categories and diets.

"Mediterranean diet"

The diet that is the subject of the health claim is the "Mediterranean diet" related to the following claimed effect: cardiac function.

The characterisation provided by Member States specifies such diet as "based on high consumption of fruits, vegetables, cereals, pulses, nuts and seeds; moderate consumption of dairy products, fish, poultry and eggs and little use of red meat; low to moderate amount of wine; olive oil is the main cooking and dressing oil". However, the Panel notes that quantitative amounts and appropriate characterisation of the food items or food groups listed have not been provided, and that no reference to the macronutrient composition (including dietary fibre) of the diet has been made. The Panel also notes that wine, which is listed as one of the components of the "Mediterranean diet", contains more than 1.2 % alcohol by volume and therefore should not bear health claims in accordance with Regulation (EC) No 1924/2006.

The Panel notes that different definitions of "Mediterranean diet" have been used in the references provided, and that therefore, the diet, which is the subject of the health claim, is unclear.

The Panel considers that the diet, "Mediterranean diet", which is the subject of the health claim, is not sufficiently characterised.

On the basis of the data presented, the Panel concludes that a cause and effect relationship cannot be established between the consumption of a "Mediterranean diet" and the claimed effect proposed because of the insufficient characterisation of the term "Mediterranean diet".

KEY WORDS

Fruits, vegetables, fruit-rich diet, vegetable-rich diet, Mediterranean diet, health claims.

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[4] submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out[5]. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

The approach used in the evaluation of Article 13(1) health claims is explained in the general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims[6].

In assessing each specific food/health relationship that forms the basis of a health claim the NDA Panel considers the extent to which:

1. the food/constituent is defined and characterised;

2. the claimed effect is defined and is a beneficial physiological effect ("beneficial to human health");

3. a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use).

Substantiation of the claim is dependent on a favourable outcome of the assessment of 1, 2 and 3 above. Thus, a cause and effect relationship is considered not to be established if the outcome of any one of these assessments is unfavourable.

For a claim, each relationship between a food/constituent and a claimed effect is assessed separately, and individual assessments are combined, as appropriate, to form coherent opinions.

1. Characterisation of the food/constituent

1.1. Fruits and/or vegetables (ID 1212, 1213, 1214, 1217, 1218, 1219, 1301, 1425, 1426, 1427, 1428, 1429, 1430)

The foods that are the subject of the health claims are "fruits (fresh, frozen, canned, bottled, dried, juiced)", "fruit-rich diet", "vegetables (fresh, frozen, canned, bottled, dried, juiced)", "vegetable-rich diet", and "fruits and vegetables" related to the following claimed effects: cardiac function, weight management, and blood glucose control.

The macronutrient composition and energy density of different fruits and fruit products is widely variable. For example, fresh fruits generally have a low the energy density, have fructose as the

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

[5] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

[6] See footnote 5

predominant sugar, and contain variable amounts of (generally soluble) dietary fibre, whereas the energy density of dried fruits is higher owing to dehydration; fruit juices can contain large amounts of added sugars, particularly glucose and sucrose, and the amount of dietary fibre is generally very low, unless it is added in the manufacturing process. The macronutrient composition and energy density of different vegetables and vegetable products is also widely variable. The energy density of fresh vegetables is generally low, and they contain variable amounts of dietary fibre, whereas processed vegetable products may contain considerable amounts of fat. Also the type and amount of vitamins, minerals, carotenoids and phenolic compounds contained in different types of fruits and vegetables is very variable.

The Panel notes that the type and amount of the specific fruits/vegetables and/or of the fruit/vegetable products required to obtain the claimed effects have not been indicated in the information provided, and that the significant differences in composition existing between such fruit/vegetable products may have an impact on the claimed effects. The Panel also notes that the health effects of "fruit-rich" and "vegetable-rich" diets may depend on the overall characteristics (e.g. energy, energy density, and macronutrient composition) of such diets as influenced by other foods.

The references submitted for the scientific substantiation of the health claims included narrative reviews and consensus opinions which addressed the association between dietary patterns and lifestyle factors (e.g. physical activity) on the risk of chronic disease, including coronary heart disease, obesity and type 2 diabetes (e.g. Lichtenstein et al., 2006; WHO/FAO, 2003). Dietary patterns which include a high consumption of fruits and vegetables have been associated with a decreased risk of chronic diseases (e.g. coronary heart disease, obesity and type 2 diabetes (WHO/FAO, 2003)) as compared to dietary patterns, amongst others, characterised by low consumption of fruits and vegetables (Lichtenstein et al., 2006; WHO/FAO, 2003). However, the food items which are included in the "fruit" and "vegetable" categories are generally not reported in these studies, and the evidence provided by these studies relates to overall dietary patterns rather than to an effect of "fruit" and "vegetable" consumption independent of other dietary modifications. Accordingly, dietary recommendations for the primary prevention of such diseases generally include consumption of a diet rich in fruits and vegetables, together with an appropriate intake of other foods to achieve dietary balance of fat/fatty acids, carbohydrates, adequate intake of dietary fibre and limited intake of sodium and alcohol.

The references submitted also included human observational studies and narrative reviews on the association between dietary patterns and consumption of vitamins, minerals, carotenoids and phenolic compounds on the risk of chronic disease and on markers of oxidative stress; human intervention studies on the effects of different fruits and vegetables, and fruit and vegetable products (e.g. red grape fruit, citrus fruit, purple grape juice, strawberries, cherries, tea, and coffee) on platelet aggregation, markers of inflammation and oxidative damage to molecules; and references on the effects of plant food processing on the content and bioavailability of phenolic compounds in the final products (e.g. green beans, sweet corn, and lettuce).

The Panel notes that most of the references provided have not characterised the intake of fruits/vegetables or of fruit/vegetable products by type and amount, or have not assessed the effects of fruit and vegetable consumption independent of other dietary modifications, but rather the effects of overall dietary patterns or the effects of specific food constituents (e.g. phenolic compounds and their classes, antioxidant vitamins, certain minerals, and dietary fibre) present in plant foods. The Panel also notes that the remaining references provided, which investigated the effects of a particular intervention on different health outcomes, referred to very specific food products, generally characterised by their antioxidant capacity *in vitro* or by their polyphenol content (and their classes), and that none of these studies addressed health outcomes related to normal cardiac function, body weight changes or blood glucose control.

The Panel considers that because of the high variety of the foods and food products that are the subject of the health claims, "fruits (fresh, frozen, canned, bottled, dried, juiced)", "fruit-rich diet", "vegetables (fresh, frozen, canned, bottled, dried, juiced)", "vegetable-rich diet", "fruits and vegetables", these foods are not sufficiently characterised in relation to the claimed effects considered in this section.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of "fruits (fresh, frozen, canned, bottled, dried, juiced)", "fruit-rich diet", "vegetables (fresh, frozen, canned, bottled, dried, juiced)", "vegetable-rich diet" or "fruits and vegetables" and the claimed effects considered in this section because of the insufficient characterisation of these food categories and diets.

1.2. "Mediterranean diet" (ID 1423)

The diet that is the subject of the health claim is the "Mediterranean diet" related to the following claimed effect: cardiac function.

The characterisation provided by Member States specifies such diet as "based on high consumption of fruits, vegetables, cereals, pulses, nuts and seeds; moderate consumption of dairy products, fish, poultry and eggs and little use of red meat; low to moderate amount of wine; olive oil is the main cooking and dressing oil". However, the Panel notes that quantitative amounts and appropriate characterisation of the food items or food groups listed have not been provided, and no reference to the macronutrient composition (including dietary fibre) of the diet has been made. The Panel also notes that wine, which is listed as one of the components of the "Mediterranean diet", contains more than 1.2 % alcohol by volume and therefore should not bear health claims in accordance with Regulation (EC) No 1924/2006.

Most of the references provided for the scientific substantiation of the claim reported on human observational studies which addressed the association between some dietary patterns defined as typical of the "Mediterranean diet", or specific components of it, and different health outcomes, including blood lipids, blood pressure, obesity, incidence of coronary heart disease, and death from cardiovascular disease and from all causes. Human intervention studies on the effects on various health outcomes of different dietary interventions, collectively designated as the "Mediterranean diet", have also been provided.

In these studies, the characterisation of the "Mediterranean diet" is very variable. Some studies only referred to the fatty acid composition of the diet, or only considered the addition of nuts or wine (reviewed in Serra-Majem et al., 2006); other studies used the "Mediterranean Adequacy Index" obtained by dividing the sum of total energy percentages from food groups "typical of the reference Mediterranean diet" (i.e. bread, cereals, legumes, potatoes, vegetables, fresh fruit, fish, wine, vegetable oils) by the sum of the total energy percentage from food groups (milk, cheese, eggs, animal fats and margarines, sweet beverages, cakes/pie/cookies, sugar) "less typical" of the "reference Mediterranean diet" (Fidanza et al., 2004); finally, some studies used different scales indicating the degree of adherence to the "traditional Mediterranean diet" with scores which were either calculated on the basis of the mean consumption of a series of "food groups" (e.g. vegetables, legumes, fruits and nuts, cereal, fish, meat, poultry, and diary products) within the same study population (Panagiotakos et al., 2005; 2006a; 2006b; Psaltopoulou et al., 2004; Trichopoulou et al., 2003; 2005) or on the basis of fixed thresholds of intake using similar "food groups" (Estruch et al., 2006; Martinez-Gonzalez et al., 2004).

The Panel notes that different dietary patterns exist in different Mediterranean countries (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010).

The Panel notes that different definitions of "Mediterranean diet" have been used in the references provided, and that therefore the diet which is the subject of the health claim is unclear.

The Panel considers that the diet, "Mediterranean diet", which is the subject of the health claim, is not sufficiently characterised.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of a "Mediterranean diet" and the claimed effect considered in this section because of the insufficient characterisation of the term "Mediterranean diet".

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

Fruits and/or vegetables

- The foods that are the subject of the health claims are "fruits (fresh, frozen, canned, bottled, dried, juiced)", "fruit-rich diet", "vegetables (fresh, frozen, canned, bottled, dried, juiced)", "vegetable-rich diet" and "fruits and vegetables" related to the following claimed effects: cardiac function, weight management, and blood glucose control. Because of the high variety of the foods and food products that are the subject of the health claims, "fruits (fresh, frozen, canned, bottled, dried, juiced)", "fruit-rich diet", "vegetables (fresh, frozen, canned, bottled, dried, juiced)", "vegetable-rich diet", "fruits and vegetables", these foods are not sufficiently characterised in relation to the claimed effects proposed.

- A cause and effect relationship cannot be established between the consumption of "fruits (fresh, frozen, canned, bottled, dried, juiced)", "fruit-rich diet", "vegetables (fresh, frozen, canned, bottled, dried, juiced)", "vegetable-rich diet" or "fruits and vegetables" and the claimed effects proposed because of the insufficient characterisation of these food categories and diets.

"Mediterranean diet"

- The diet that is the subject of the health claim, is the "Mediterranean diet" related to the following claimed effect: cardiac function. The "Mediterranean diet", which is the subject of the health claim, is not sufficiently characterised.

- A cause and effect relationship cannot be established between the consumption of a "Mediterranean diet" and the claimed effect proposed because of the insufficient characterisation of the term "Mediterranean diet".

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1950, EFSA-Q-2008-1951, EFSA-Q-2008-1952, EFSA-Q-2008-1955, EFSA-Q-2008-1956, EFSA-Q-2008-1957, EFSA-Q-2008-2039, EFSA-Q-2008-2160, EFSA-Q-2008-2162 ,EFSA-Q-2008-2163, EFSA-Q-2008-2164, EFSA-Q-2008-2165, EFSA-Q-2008-2166, EFSA-Q-2008-2167). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[7] (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

a) the role of a nutrient or other substance in growth, development and the functions of the body; or

b) psychological and behavioural functions; or

c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[8]

Foods are commonly involved in many different functions[9] of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

[7] OJ L12, 18/01/2007
[8] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[9] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

(a) the claimed effect of the food is beneficial for human health,

(b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

(c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity

consumed.

- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to fruits and/or vegetables and to "Mediterranean diet", including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1212	Fruits (fresh, frozen, canned, bottled, dried, juiced).	Heart health. Clarification provided Contribute and support cardiovascular/heart health (WHO Report 2003, cpt 5.4, table 10): Promote and mantain cardiovascolar health via the action of phytochemicals eating at least 400g/day of fruit and vegetables.	Diets rich in fruit promote heart health.
	Conditions of use - 5 a day (80g = 1 portion; only one portion can be juice at 150ml) - At least 400 g/day of fruit and vegetables, at least 5 portions/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1213	Fruits (fresh, frozen, canned, bottled, dried, juiced).	Weight management via fibre. Clarification provided Weight control via dietary fibre and satiety (WHO report 2003 table 7 and Annex: Summary of evidence).	A diet rich in fruits helps to manage body weight.
	Conditions of use - 5 a day (80g = 1 portion; only one portion can be juice at 150ml). - At least 400 g/day of fruit and vegetables, at least 5 portions/day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1214	Fruits (fresh, frozen, canned, bottled, dried, juiced).	Modulation of glycemic response.	A diet rich in fruits helps to control blood glucose level.
	Conditions of use - 5 a day (80g = 1 portion; only one portion can be juice at 150ml). - At least 400 g/day of fruit and vegetables, at least 5 portions/day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1217	Vegetables (fresh, frozen, canned, bottled, dried, juiced).	Heart health. Clarification provided	A diet rich in vegetables promotes heart health.

		Promote and mantain cardiovascular health via the action of phytochemicals eating at least 400g/day of fruit and vegetables.	
	Conditions of use - 5 a day (80g = 1 portion; only one portion can be juice at 150ml).		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1218	Vegetables (fresh, frozen, canned, bottled, dried, juiced).	Weight management via fibre. Clarification provided Weight control via dietary fibre and satiety (WHO report 2003 table 7 and Annex: Summary of evidence).	A diet rich in vegetables helps to manage body weight.
	Conditions of use - 5 a day (80g = 1 portion; only one portion can be juice at 150ml).		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1219	Vegetables (fresh, frozen, canned, bottled, dried, juiced).	Modulation of glycemic response.	A diet rich in vegetables helps to control blood glucose level.
	Conditions of use - 5 a day (80g = 1 portion; only one portion can be juice at 150ml).		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1301	Fruits and vegetables.	Heart and cardiovascu-lar system. Clarification provided In the frame of healthy diet consumption of at least 400 g/day fruit and vegetable is suggested. Fibres, antioxodant vitamins and minerals and other bioactive substances (polyphenols, phytosterines,saponines, ect.) can affect the circulatory system (heart, wessels, blood parameters) in a positive way.	Regular consumption of fruit and vegetables support the heart and cardiovascular health.
	Conditions of use - Regular consumption several times a day, together >400 g/day.		

	Comments from Member States This health relationship can be classified as a general dietary guideline, but as a part of commercial communication it should be handled under Reg. 1924/2006/EK.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1423	Mediterranean diet.	Related to cardiovascular health. Clarification provided Sustains/ supports cardiovascular health: for example, may help maintain a normal blood pressure and normal cholesterol levels and trials show reduced incidence and prevelance of cardiac events in subjects on a Mediterranean diet compared to controls. Such a diet is based on high consumption of fruits, vegetables, cereals, pulses, nuts and seeds; moderate consumption of dairy products, fish, poultry and eggs and little use of red meat; low to moderate amount of wine; olive oil is the main cooking and dressing oil.	'X' fits in a Mediterranean diet. A Mediterranean style diet helps maintain heart health.
	Conditions of use - See reference section for dietary characteristics. Product should provide at least a serving of fruit and/or vegetables and/or meet the conditions of use for unsaturated fatty acids.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1425	Fruit-rich diet.	Heart health. Clarification provided Contribute and support cardiovascular/heart health (WHO Report 2003, cpt 5.4, table 10).	A diet rich in fruit promotes heart health.
	Conditions of use - At least 400 g/day of fruit and vegetables, at least 5 portions/day.		

ID	Food or Food constituent	Health Relationship	Proposed wording
1426	Fruit-rich diet.	Weight management via fibre.	A diet rich in fruits can help to control body weight.
	Conditions of use - At least 400 g/day of fruit and vegetables, at least 5 portions/day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1427	Fruit-rich diet.	Modulation of glycemic response.	A diet rich in fruits helps to control blood glucose level.
	Conditions of use - At least 400 g/day of fruit and vegetables, at least 5 portions/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1428	Vegetable-rich diet.	Heart health. Clarification provided Contribute and support cardiovascular/heart health (WHO Report 2003, cpt 5.4, table 10).	Diets rich in vegetables promote heart health.
	Conditions of use - At least 400 g/day of fruit and vegetables, at least 5 portions/day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1429	Vegetable-rich diet.	Weight management via fibre.	A diet rich in vegetables helps controlling body weight.
	Conditions of use - At least 400 g/day of fruit and vegetables, at least 5 portions/day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1430	Vegetable-rich diet.	Modulation of glycemic response.	A diet rich in vegetables helps controlling blood glucose level.
	Conditions of use - At least 400 g/day of fruit and vegetables, at least 5 portions/day.		